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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,333	02/28/2001	Brian Miki	1096.001C	5110

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HESLIN ROTHENBERG FARLEY & MESITI PC  
5 COLUMBIA CIRCLE  
ALBANY, NY 12203

EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicant(s)

09/673,333

Applicant(s)

MIKI ET AL.

Examiner

Cynthia Collins

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 11-20, 22-28, 30-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 21 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-10, 21 and 29, directed to an isolated genomic DNA sequence characterized by the restriction map of Figure 11(a) (SEQ ID NO:8), is acknowledged. Claims 11-20, 22-28 and 30-44, and the nonelected sequences, are withdrawn from consideration as being directed to nonelected inventions.

### ***Information Disclosure Statement***

Applicant's IDS, filed April 1, 2003, Paper No. 11, was not available for consideration at the time of the instant office action.

### ***Specification***

The abstract of the disclosure is objected to because it was not submitted on a separate sheet. Correction is required.

The title of the invention is not descriptive because it is not commensurate in scope with the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

***Claim Objections***

Claim 21 is objected to for failing to comply with 37 CFR 1.821(d), in that reference is not made to the DNA in Figure 11(a) by use of a sequence identifier preceded by "SEQ ID NO:" in the text of the claims. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated genomic DNA of any structure and of any function obtained from any seed plant that is differentially expressed in seed coat tissues, including the outer integument, the inner integument, the thick walled parenchyma, the thin walled parenchyma, the endothelium, the hourglass cells, the palisade, the stellate parenchyma, and the membranous endocarp.

In contrast, the specification describes only five isolated genomic DNAs, four obtained from soybean (including the elected SC20 genomic DNA of SEQ ID NO:8), and one obtained from tobacco. The specification does not describe the five isolated genomic DNAs as having any

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common structural features, or any common functional features other than that all are expressed in seed coat tissues. Furthermore, while the specification describes SEQ ID NO:8 as being expressed in the thick-walled parenchyma of the outer integument of the seed coat, the specification does not describe SEQ ID NO:8 as being expressed in the inner integument, the thin walled parenchyma, the endothelium, the hourglass cells, the palisade, the stellate parenchyma, or the membranous endocarp (pages 33-36; 52-54; 57-58; 61-62; 65-68).

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description

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Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 21 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 and 29 are indefinite in the recitation of "differentially expressed", as "differentially expressed" is a relative phrase that lacks a comparative basis.

Claim 21 is indefinite because it is unclear in what way the isolated genomic DNA is "characterized by" the restriction map of Figure 11 (a). It is unclear whether the claimed DNA is merely identical in sequence to the DNA represented by the restriction map of Figure 11 (a) (SEQ ID NO:8), or whether the claimed DNA is a DNA of any sequence that has the same restriction sites in the same order and separated by the same distance as the DNA represented by the restriction map of Figure 11 (a).

***Claim Rejections - 35 USC § 101 and 35 USC § 112***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10, 21 and 29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-10 and 29 are drawn to an isolated genomic DNA of any structure and of any function obtained from any seed plant that is differentially expressed in seed coat tissues. Claim 21 is drawn to an isolated genomic DNA characterized by the restriction map of Figure 11(a) (the SC20 genomic DNA of SEQ ID NO:8).

The specification discloses that the elected SC20 genomic DNA of SEQ ID NO:8 was obtained from soybean, is expressed in the thick-walled parenchyma of the outer integument of the seed coat, encodes a putative protein of 770 amino acids that is similar in structure to proteins of the Pyrolysin family of subtilase serine proteases, and contains 3 potential transcription start sites at nucleotides 1085, 1156 and 2272 (pages 33-36; 52-54; 57-58; 61-62; 65-68). The specification does not, however, disclose or assert any specific and substantial or well established utility for the elected SC20 genomic DNA of SEQ ID NO:8.

First, the claims do not recite a specific functional utility for the claimed isolated genomic DNAs. Although the claims recite that the isolated genomic DNAs are differentially expressed in seed coat tissues, such a limitation merely indicates the spatial location of transcription of the native genomic DNA sequence, rather than a functional utility for the claimed isolated genomic DNA sequence. Because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility cannot be assessed.

Second, the claimed invention lacks utility because no function has been demonstrated for the elected SC20 genomic DNA of SEQ ID NO:8. Although the specification reveals that the

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genomic DNA of SEQ ID NO:8. encodes a putative protein of 770 amino acids that is similar in structure to proteins of the Pyrolysins family of subtilase serine proteases, the specification does not disclose the nature or extent of the correlation, if any, between the regions of amino acid sequence homology and the known functional domains of subtilase serine proteases. The specification also does not provide any empirical data to support any specific function for the putative protein encoded by SEQ ID NO:8, or for the genomic DNA of SEQ ID NO:8. While the state of the art recognizes that a functional assignment based on sequence comparisons may categorize a protein into a particular class, or provide a starting point for verifying protein activity, it does not replace empirical data or further structural analysis for confirming protein activity, as general structural homology between amino acid sequences is not always predictive of their functional homology. For example, Doerks et al. teach that incorrect or incomplete sequence information within a database affects the predictive capacity of the database (Trends in Genetics, 1998, Vol. 14, No. 6, pages 248-250, see page 248 column 1 paragraph 1). Doerks et al. also teach that query searches may identify shared homology with multiple groups of functionally unrelated proteins (Page 248 column 3 second full paragraph), that regions of shared homology may be nonfunctional regions (Page 248 column 3 third full paragraph), and that the degree of shared homology within a functional region does not always predict a conservation of the functional mechanism of that region (Page 248 column 3 fourth full paragraph).

Third, the elected SC20 genomic DNA of SEQ ID NO:8 lacks utility under current utility guidelines. The specification does not disclose or assert any specific and substantial or well established utility for the elected SC20 genomic DNA of SEQ ID NO:8. Applicant does not teach how the claimed genomic DNA would be substantially beneficial to the public. Although



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genomic DNA sequences for which a specific function has been demonstrated may have a well established utility, genomic DNA sequences for which no function has been demonstrated do not have a well established utility. It is apparent that extensive further research, not considered to be routine experimentation, would be required before one of skill in the art would know how to use the claimed invention. It has been established by the courts that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility.

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (*Brenner v. Manson*, 383 U.S. 519 (1966)).

Thus, while a genomic DNA sequence that exhibits a specific function may have a substantial benefit to the public, Applicant does not disclose that SEQ ID NO:8 has a specific function, and one skilled in the art cannot conclude that SEQ ID NO:8 has a specific function based upon Applicant's disclosure. Applicant's invention is not refined to the point where specific benefit exists in currently available form. As set forth above, one skilled in the art cannot readily take Applicant's claimed invention and derive immediate benefits from it based upon Applicant's disclosure. Accordingly, the claimed invention lacks a real world use. (see Utility Examination Guidelines published in the Federal Register, Vol. 66, No. 4, Friday, January 5, 2001, Notices, pages 1092-1099).

Claims 1-10, 21 and 29 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific or substantial

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asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Fobert et al. (The Plant Journal, 1994, Vol. 6, No. 4, pages 567-577, Applicant's IDS).

The claims are drawn to an isolated genomic DNA of any structure and of any function obtained from any seed plant that is differentially expressed in seed coat tissues, including the outer integument, the inner integument, the thick walled parenchyma, the thin walled parenchyma, the endothelium, the hourglass cells, the palisade, the stellate parenchyma, and the membranous endocarp.

Fobert et al. teach an isolated genomic DNA obtained from tobacco that is differentially expressed in seed coat tissues (page 569 Figure 2; page 572 Figure 7). While Fobert et al. do not explicitly teach that their genomic DNA is differentially expressed in the outer integument, the inner integument, the thick walled parenchyma, the thin walled parenchyma, the endothelium, the hourglass cells, the palisade, the stellate parenchyma, and the membranous endocarp of the seed coat, the genomic DNA taught by Fobert et al. would necessarily be expressed in these seed

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coat tissues, as the function of a DNA molecule is determined by its structure, and the genomic DNA taught by Fobert et al. meets all the structural limitations set forth in the rejected claims.

***Remarks***

No claim is allowed.

Claim 21 is deemed free of the prior art due to the failure of the prior art to teach or suggest the SC20 genomic DNA of SEQ ID NO:8.

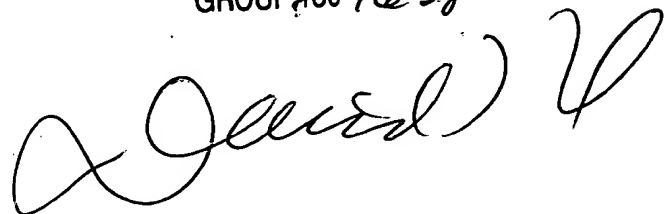
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

A large, stylized handwritten signature in black ink, likely belonging to David T. Fox, is written over the printed name and group number.